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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Davidson, Davidson & Kappel, LLC
14th Floor
485 Seventh Avenue
New York, NY 10018

EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/045,607	**Applicant(s)** TAVARES ET AL.	
	Examiner Isis A. Ghali	**Art Unit** 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 May 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *18 May 2010*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *8-11,13,14,16, 20, 22-24, 29, 30, 32-38 and 40-55*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

Claims 8-11, 13, 14, 16, 20-24, 29, 30, 32-38, and 40-55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,910,205 ('205) in view of applicants' admission in paragraph 0123 and US 5,968,547 ('547).

(1) Applicants argue that it is improper to use the present specification as an "instruction manual or 'template' to piece together teachings of prior art" to arrive at the claimed invention. "To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction-- an illogical and inappropriate process by which to determine patentability."
In response to this argument, it is argued that MPEP 2129[R-6] stated that "A statement by an applicant in the specification or made during prosecution identifying the work of another as "prior art" is an admission which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. Riverwood Int 'l Corp. v. R.A. Jones & Co., 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); Constant v. Advanced Micro-Devices Inc., 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988)." "However, even if labeled as "prior art," the work of the same inventive entity may not be considered prior art against the claims unless it falls under one of the statutory categories. Id.; see also Reading & Bates Construction Co. v. Baker Energy Resources Corp., 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984) ("[W]here the inventor continues to improve upon his own work product, his foundational work product should not, without a statutory basis, be treated as prior art solely because he admits knowledge of his own work. It is common sense that an inventor, regardless of an admission, has knowledge of his own work.")." Therefore, the admission in the present specification qualifies as prior art.

Applicants argue that the Examiner acknowledged on page 5 of the Office Action that the Kogan reference "does not teach the specific delivery profile of loratadine," and did not contend that the Reder reference (which does not mention loratadine) describes the "desired pharmacokinetic" parameters of loratadine. In making the rejection, the Examiner relied on the present specification (i.e., the paragraph bridging page 23 and 24, describing the calculations of the dosing rate suggested by the Applicants, and the first full paragraph on page 24, stating that "any type of transdermal delivery system may be used in accordance with the methods of the present invention so long as the desired pharmacokinetic and pharmacodynamic response[s] are attained") and used this disclosure to combine the cited references and assert that the cited references render the present claims obvious. Moreover, there is nothing in the cited references that links the presently claimed plasma level of loratadine at steady state with the presently claimed mean relative release rates of loratadine at three different time points (24, 48 and 72 hours).
In response to this argument, it is argued that the present claims as a whole is taught by the combination of the prior art, therefore, prima facie case of obviousness has been established in the meaning of USC 103 (a). Further, Kogan teaches that the dose of loratadine may be varied depending on the weight and age of the patient, and may also depend upon the severity of the condition being treated (col.3, lines 56-60). Therefore, one having ordinary skill in the art would have been able to determine the desired release rate of loratadine according to individual patient and severity of the allergic condition to be treated by manipulating the dose of loratadine and delivering formulation in view of doses and release rates disclosed by Kogan and the formulation disclosed by Reder. Therefore, the claimed release rates and times are met by the reference. Further, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071,5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Loratadine was known at the time of the invention to be administered transdermally as disclosed by Kogan. Reder taught that when the drug is included in the described transdermal device, the drug follows and is delivered according to its pharmacokinetics for period of 5 days as desired by applicants. Applicants disclosed in paragraph 0123 that the release rate for a loratadine transdermal delivery system was calculated from the drug bioavailability available data. Applicants also admit in the same paragraph that any type of transdermal delivery system may be used in accordance with the methods of the present invention so long as the desired pharmacokinetic are attained over at least 3 days to about 8 days. Therefore, one having ordinary skill in the art at the time of the invention would deliver loratadine transdermally as taught by Kogan using the device taught by Reder and would calculate the transdermal release rates from the loratadine bioavailability available data to achieve a transdermal delivery device having the structure and reservoir formulation comprising polymer, softener, solvent and loratadine that delivers loratadine at a delivery rate in accordance to its pharmacokinetics to treat patients suffering from allergic reactions with great success. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir.1992). In this case, the cited prior art in the field of applicant's endeavor since both Kogan and Reder are concerned about transdermal delivery of active agents over 3-5 days following the pharmacokinetics of the drug that is attained by specific structure and formulation of a transdermal drug delivery system, and their combination is reasonable as stated above.

Applicants argue that it is only through the impermissible use of information learned from the present specification that the Examiner is able to combine the cited references and assert that the present claims are rendered obvious by the combination of the cited references.
In response to this argument, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(2) The claimed steady state plasma level of loratadine cannot be expected from the cited references Applicants argue that the steady state plasma level of loratadine calculated from the data provided in the Kogan reference using the available pharmacokinetic information about loratadine is different from the steady state plasma level of loratadine recited in the present claims. Accordingly, the claimed steady state plasma level of loratadine cannot be expected from the Kogan reference. As there is no mention of any loratadine formulations in the Reder reference, the claimed steady state loratadine concentration also cannot be expected from the Reder reference.

In response to this argument, it is argued that Kogan teaches that the dose of loratadine may be varied depending on the weight and age of the patient, and may also depend upon the severity of the condition being treated (col.3, lines 56-60). The frequency of dosage application according to Kogan can be once every 3 days to once every 7 days (col.4, lines 5-10). Therefore, one having ordinary skill in the art would have been able to determine the desired release rate of loratadine according to individual patient and severity of the allergic condition to be treated by manipulating the dose of loratadine and delivering formulation in view of doses and release rates disclosed by Kogan and the formulation disclosed by Reder. Further, Kogan teaches mean average release rate from 1.4 ug/cm2/hr to 14 ug/cm2/hr and applicant claim mean average release rate from 1.8 ug/cm2/hr to 9.9 ug/ cm2/hr, which falls within the values disclosed by the reference. Further Kogan teaches release for many days. Therefore, the claimed release rates and times are met by the reference. Result-effective variables can be optimized. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)

(3) The claimed release profile of loratadine is not suggested by the cited references. Applicants argue that the claimed steady state plasma level of loratadine is not taught or suggested by the cited references. The only connection between the presently claimed plasma level of loratadine at steady state with the presently claimed mean relative release rates of loratadine at three different time points (24, 48 and 72 hours) is in the present specification, rather than in the cited references. Applicants argue that the combination of the cited references does not teach the same drug in the same formulation.
In response tot his argument, it is repeated that one having ordinary skill in the art at the time of the invention would deliver loratadine transdermally as taught by Kogan using the device taught by Reder and would calculate the transdermal release rates from the loratadine bioavailability available data to achieve a transdermal delivery device having the structure and reservoir formulation comprising polymer, softener, solvent and loratadine that delivers loratadine at a delivery rate in accordance to its pharmacokinetics to treat patients suffering from allergic reactions with great success. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir.1992). In this case, the cited prior art in the field of applicant's endeavor since both Kogan and Reder are concerned about transdermal delivery of active agents over 3-5 days following the pharmacokinetics of the drug that is attained by specific structure and formulation of a transdermal drug delivery system, and their combination is reasonable as stated above. The invention as a whole is taught by the combination of the references; therefore, prima facie case of obviousness has been established in the meaning of USC 103 (a). Again, Kogan teaches loratadine administered transdermally and it is evident from the disclosure of Reder that when the drug is included in the described transdermal device, the drug follows and is delivered according to its pharmacokinetics for period of 5 days as desired by applicants. The structure and formulation of the reservoir of the present transdermal device are identical to that of Reder. Applicants disclosed in paragraph 0123 that the release rate for a loratadine transdermal delivery system was calculated from bioavailability available data. Applicants also admit in the same paragraph that any type of transdermal delivery system may be used in accordance with the methods of the present invention so long as the desired pharmacokinetic are attained over at least 3 days to about 8 days. At the time of the invention, one having ordinary skill in the art looking for a structure for transdermal patch for sustained release of drug and knowing the properties of the drug intended to be delivered, would have looked at Reder's patent or any other patent delivering drug transdermally. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Finally, it is well established that the claims are given the broadest reasonable interpretation during examination in light of the supporting disclosure as it would be interpreted by one of ordinary skill in the art, In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023,1027-28 (Fed. Cir. 1997); In ream. Acad. ofScL Tech. Ctr., 367 F.3d 1359,1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Further, it has been held that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004). In the present case, the term "about 3 ng/ml" encompasses values more than the claimed value.